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Er 2438. (Once Amended) The method of claim 27 further comprising administering an insulin.

### REMARKS

#### Claim Amendments

The present amendments are made, not for reasons related to patentability, but to correct the numbering of claims from which the amended claims depend. The implied scope of the claims remains unchanged.

In accordance with 37 C.F.R. §1.121, a marked up copy of the amended claims is appended hereto. Additions are noted by underlining. Deletions are noted by bracketing.

#### The Double Patenting Rejection

Claims 15-39 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 38-47 of copending application number 08/737,446 in view of WO 93/18786. This rejection is traversed.

To sustain this rejection, the Patent Office must meet its burden under a one-way determination of obviousness. In re Berg, 46 USPQ2d 1226 (Fed. Cir. 1998) That is, the Patent Office would need to prove that the methods recited in present claims 15-39 are obvious variations of the methods defined in claims 38-47 of copending application number 08/737,446 in view of WO 93/18786.

Oral or nasal administration, the routes of administration set forth in present claims 38-52, however, would not have been obvious in view of subcutaneous administration, the route of administration set forth in claims 38-47 of copending application number 08/737,446. Notably, for example, subcutaneous administration is both technically distinct and is invasive, while oral and nasal administration is not. The Patent Office, apparently agreeing with Applicant that oral or nasal administration is not obvious in view of subcutaneous administration, attempts to sustain this rejection by referring to a secondary document, WO 93/18786. Yet, in doing so, the Patent Office has not established that one of skill in the art would be motivated to modify the methods set forth in claims 38-47 of copending application number 08/737,446 with the disclosure of WO 93/18786, nor that such modification would result in the invention recited in present claims 15-39.

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The Manual of Patent Examining Procedure §804.02, citing Quad Environmental Technologies Corp. v. Union Sanitary District, F.2d 870, 20 USPQ2d 1392 (Fed. Cir. 1991), states that the "filing of a terminal disclaimer to obviate a rejection based on nonstatutory double patenting is not an admission of the propriety of the rejection." Given that fact, and the fact that the term of any patent issuing from the subject application or that having application number 08/737,446 would be the same, a terminal disclaimer is being filed herewith merely in order to expedite prosecution. Hence, this rejection is rendered moot, and withdrawal of the rejection is proper and hereby requested.

#### The 35 U.S.C. §112, First Paragraph, Rejection

Claims 37-39 stand rejected under 35 U.S.C. §112, First Paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. This rejection is respectfully traversed.

In the Final Office Action, the Patent Office referred to the recited phrase "glucagon-like peptide 1 related peptide" in proposing a rejection for alleged lack of written description support. During the telephonic interview with Applicant's Representatives on May 21, 2002, however, reference was made to the fact that the phrase "glucagon-like peptide 1-related peptide" is literally set forth in the originally filed specification (for example, see page 4, lines 26-30; also see page 8, lines 9-11), and the fact that the Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶1, "Written Description" Requirement, published in the Federal Register on January 5, 2001, state: "There is a strong presumption that an adequate written description of the claimed invention is present in the specification as filed."<sup>1</sup> The Examiner agreed to withdraw this rejection.

#### Information Disclosure Statement

Finally, an initialed copy of the Form PTO/SB/08A submitted with the Information Disclosure Statement on June 5, 2001, has not been returned to Applicant. Applicant requests that such a copy be provided with the mailing of the next Communication from the Patent Office.

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<sup>1</sup> See Section II.A. thereof.

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Respectfully Submitted,

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**MARKED UP VERSION OF AMENDED CLAIMS**

Please amend the application as follows:

In the Claims

36. (Once Amended) The method of claim [48] 35 further comprising administering an insulin.
38. (Once Amended) The method of claim [50] 37 further comprising administering an insulin.

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